

Express Mail Label No.: EV39952522SUS

1 of 2

Date of Deposit: January 7, 2005

/ Please type a plus sign (+) in this box

PTO/SB (12-97)
OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	10/628,965
	Filing Date	07/28/03
	First Named Inventor	Keller
	Group Art Unit	1616
	Examiner Name	Haghighatian
	Attorney Docket Number	28069-606 CON

U.S. PATENT DOCUMENTS

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date

FOREIGN PATENT DOCUMENTS

Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
M	B1	EP 0 416 950	Glaxo Group Limited	September 7, 1990	X
I	B2	EP 0 416 951	Glaxo Group Limited	September 7, 1990	X
	B3	WO 93/11773	Aktiebolaget Astra	June 24, 1993	X
M	B4	WO 00/53157	Chiesi Farmaceutici S.P.A.	September 14, 2000	X

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
M	C1	Adjei and Gupta, In <u>Inhalation Delivery of Therapeutic Peptides and Proteins</u> , Adjei and Gupta eds., Marcel Dekker, Inc., New York, 1997, Chapter 22, pages 625-637.
M	C2	Bolhuis and Lerk (1981). <i>J. Pharm. Pharmacol.</i> 33: 790.
M	C3	Braun et al. (1996). <i>Int. J. Pharm.</i> 135: 53-62.
	C4	British Pharmacopoeia, pages 1173-1174. Year?
M	C5	Byron, In <u>Respiratory Drug Delivery</u> , Byron ed., CFC Press, Inc., Boca Raton, 1990, pages 169-170.
	C6	Chowhan and Chi (1986). <i>J. Pharm. Sci.</i> 75: 534-541.
	C7	Ganderton (1969). <i>J. Pharm. Pharmac.</i> 21: 9S-18S.
M	C8	Geuns et al. (1997). <i>European J. Pharm. and Biopharm.</i> 44: 187-194.
	C9	Guideline 3AQ15a, Stability Testing of New Active Substances and Medicinal Products, pages 127-141. Year?
	C10	Guideline 3AQ16a, Stability Testing on Active Substances and Finished Products, pages 143-145-151. Year?
M	C11	Handbook of Pharmaceutical Excipients, 2 nd ed., 1994, pages 280-282.
	C12	Hickey et al. (1994). <i>Pharma. Tech.</i> pages 58, 60, 62-64, and 82.
	C13	Mahmoud and El-Shaboury (1985). <i>Acta. Pharm. Fenn.</i> 94: 125-131.
M	C14	<u>Martindale: The Extra Pharmacopoeia</u> , 28 th ed., Reynolds ed., The Pharmaceutical Press, London, 1993, Abstract 6022-f.
	C15	Material Safety Data Sheet, Magnesium Stearate, Spectrum. Year?
M	C16	Meakin et al. (1995). <i>Int. J. Pharm.</i> 119: 103-108.
	C17	MIMS (Monthly Index of Medical Specialties), November 1996, pages 244-245.
M	C18	MIMS (Monthly Index of Medical Specialties), October 1998, pages 271-273.

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
M	C19	Murthy and Samyn (1977). <i>J. Phar. Sci.</i> 66: 1215-1219.
	C20	Note for Guidance on Development Pharmaceuticals, European Agency for the Evaluation of Medicinal Products, Human Medicines Evaluation Unit, CPMP/QWP/155/96, January 28, 1998.
	C21	Note for Guidance on Dry Powder Inhalers, European Agency for the Evaluation of Medicinal Products, Human Medicines Evaluation Unit, CPMP/QWP/158/96, June 24, 1998.
	C22	Peart et al. (1997). <i>Pharm. Res.</i> 14: S-142-S-143, Abstract No. 1405.
	C23	<i>Pharmaceutics: The Science of Dosage Form Design</i> , ed. Michael E. Aulton, Churchill Livingstone, Edinburgh, London, Melbourne and New York, 1988, page 56.
	C24	Price et al. (2002). <i>Int. J. Pharm.</i> 246: 47-59.
	C25	Remington's <i>Pharmaceutical Sciences</i> , 18 th ed., 1990, Chapter 31, pages 589,593, and 602; Chapter 76, pages 1451-1452; and Chapter 89, pages 1633, 1636, and 1637.
	C26	<i>Respiratory Drug Delivery II</i> , paper presented by John N. Staniforth at a meeting in Keystone, CO, March 26-30, 1990.
	C27	Statutory Declaration from Professor David Ganderton, December 15, 2003, In the Matter of an opposition by Vectura Limited to EP 1 131 059 in the name of Jago Research AG.
	C28	van Kamp et al. (1986). <i>Pharm. Acta. Helv.</i> 61: 22-29.
	C29	Young et al. (2003). <i>J. Pharm. Sci.</i> 92: 815-822.
M	C30	Zeng et al., In <i>Particulate Interactions in Dry Powder Formulations for Inhalation</i> , Taylor and Francis, Inc., New York, 2001, Sections 1.6.7 (pages 23-24) and 5.5.6 (pages 163-165).

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered	5/12/05
--------------------	---	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.